

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA,	)	Case No. 18-CR-258 EJD
	)	
Plaintiff,	)	DECLARATION OF MARCI B. NORTON
	)	
v.	)	
ELIZABETH HOLMES and RAMESH	)	
"SUNNY" BALWANI,	)	
	)	
Defendants.	)	

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Pursuant to 28 U.S.C. § 1746, I, Marci B. Norton, declare as follows:

1. I am a Senior Counsel at the Office of Chief Counsel ("OCC") at the U.S. Food and Drug Administration ("FDA"). I represent FDA in the above-captioned matter ("criminal case") and in the related matter, *Securities and Exchange Commission v. Ramesh "Sunny" Balwani*, 5:18-cv-01603-EJD ("SEC case"). The statements herein are based on my personal knowledge or review of the case record.

2. FDA received a subpoena in the SEC case from Mr. Balwani's counsel dated September 12, 2018. FDA received a "re-issued" subpoena in the same case from Mr. Balwani's counsel dated March 15, 2019.

3. The subpoenas issued by Mr. Balwani's counsel in the SEC case directed FDA to produce twenty (20) categories of documents including but not limited to "[a]ll DOCUMENTS and COMMUNICATIONS referring or relating to THERANOS, HOLMES, or BALWANI" ("Request No. 1") generally for the time period of January 2010 to June 2018.

4. FDA made its first production of documents responsive to Mr. Balwani's subpoenas on or about October 15, 2018. It made subsequent productions on or about October

17, 2018; October 19, 2018; October 24, 2018; July 10, 2019; August 16, 2019; August 23, 2019; August 30, 2019; September 25, 2019; October 1, 2019; October 8, 2019; October 9, 2019; and October 24, 2019.

5. Defendant Holmes filed a motion to compel in the criminal case on or about April 15, 2019, which Defendant Balwani joined the following day, seeking six categories of documents from FDA and other agencies. FDA interpreted the six categories of documents to be encompassed by Request No. 1 of Mr. Balwani's subpoenas in the SEC case.

6. On or about August 5, 2019 – after a supplemental protective order for FDA's documents was entered in the criminal case and the Theranos assignee had provided a waiver authorizing FDA to produce Theranos's confidential commercial and trade secret information to the parties in the criminal case – FDA provided Defendant Holmes a copy of all previous productions it had made to Defendant Balwani in the SEC case. On or about that time, FDA also authorized Defendant Balwani to use all prior FDA productions in the criminal case. All productions referenced above in Paragraph 4 of this Declaration were also provided to the Defendants for use in the criminal case.

7. FDA produced over 60,000 pages to Defendants in the criminal case by October 24, 2019. This page count does not include pages that were produced with slipsheets stating "intentionally withheld" or "technical issue."

8. This Court initially ordered FDA to produce documents to Defendants responsive to the motion to compel by October 2, 2019. By that deadline, FDA had produced all responsive, non-privileged, and non-duplicative emails and other documents that it had collected from more than 65 custodians to Defendants. FDA explained in its October 30, 2019 letter to the parties' counsel that the only documents remaining to be produced after October 2 were (a)

documents from FDA's Office of Chief Counsel, (b) documents identified as containing foreign language or technical issues, and (c) a subset of documents from two custodians who were former employees, due to technical difficulties during collection.

9. On October 2, 2019, the Court ordered FDA to complete its production by October 25, 2019. By that deadline, as FDA explained in its October 30, 2019 letter to the parties' counsel, FDA had produced the responsive, non-privileged, and non-duplicative documents from subsets (a), (b), and (c) referenced in Paragraph 8 of this Declaration, except for some documents with remaining technical issues and fewer than 300 additional documents attributable to custodian Alberto Gutierrez that needed to be reviewed after it was determined that FDA could not repair his damaged archived email file. The same letter also stated that FDA was working on collecting, searching, processing, and reviewing documents from 14 additional custodians that Defendants had requested after the FDA's October 1<sup>st</sup> production.

10. On or about October 25, 2019, it came to my attention that, for approximately 18 of the over 65 original custodians, documents from their network drive needed to be collected, reviewed, and produced. FDA began collecting those documents shortly thereafter.

11. On November 4, 2019, I, along with my colleague, Jaclyn E. Martínez Resly, participated in a hearing before the Court regarding, among other things, the status of FDA's productions and Defendants' arguments regarding alleged deficiencies with FDA's productions. When asked at the hearing whether FDA could meet an end-of-year production deadline if additional search terms were added, we stated that the Agency would do its best to do so but that if the new terms would require re-collection of documents from custodians, FDA would not be able to do so by the end of 2019. Our statements contemplated employing FDA's typical collection methods as described in more detail in Paragraph 12 of this Declaration.

12. Prior to November 2019, FDA had asked currently-employed custodians to self-collect potentially responsive documents and had undertaken – or in the case of the custodians newly identified by Defendants in October, begun – electronic collection for only a minority of the custodians (approximately twenty-three (23), many of whom were former employees). For FDA, self-collection is the typical method employed for discovery in litigation matters and for responding to Freedom of Information Act requests as the best match for FDA’s current resources and capabilities. Self-collection is currently faster for FDA than electronic collection because self-collection allows for concurrent collection by individual custodians, whereas electronic collection at FDA’s current level of deployment is subject to technological limitations that, using almost all available resources, can at best, deliver a limited number of custodians per week from one source (e.g., email).

13. The electronic collection now being employed for the vast majority of the custodians, including for the former employees who are not able to self-collect their documents, is the single largest roadblock FDA faced in meeting the Court’s December 31, 2019 deadline to produce responsive documents collected with the new search terms.

14. FDA has devoted substantial resources to meeting each of the Court’s production deadlines. For example, it sought and obtained access to an electronic document review platform through a special arrangement with the U.S. Department of Health and Human Services; expended more than an estimated 2,600 combined employee hours on document review and production through October 2019; assigned to the cases two OCC staff attorneys (including myself), two paralegals, and e-Discovery counsel who has more than 15 years’ experience in electronic discovery; and at one time diverted over 25 FDA employees from their normal duties to assist the information disclosure team in reviewing collected documents for responsiveness

and privilege. Moreover, FDA worked extensively with the prosecutors and FDA's eDiscovery team since the November 5, 2019 Order to, among other things, strategize the swiftest means of electronically collecting documents to provide to the prosecutors pursuant to the Court's November 5 and December 2, 2019 Orders; outsourced responsiveness review to the U.S. Department of Justice; and devoted nearly all OCC eDiscovery and information technology resources – including over the end-of-year holiday period – to collecting documents, notwithstanding demands from other pending cases.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on January 9, 2020.

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Marci B. Norton  
Senior Counsel  
United States Food and Drug Administration